



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,109	09/20/2005	Kensuke Egashira	082368-003100US	7458

20350 7590 04/13/2007
TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
----------	--------------

1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/526,109

Applicant(s)

EGASHIRA ET AL.

Examiner

Samuel W. Liu

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/12/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 2-3 and 6-7 are pending.

The amendment filed 2/12/07 which cancels claims 1 and 4-5 and amends claims 2 has been entered.

Election/Restrictions

The Applicant's election (filed 2/12/07) of Group II, claims 2-3 and 6-7 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 2-3 and 6-7 are under examination.

IDS

The references cited in the IDS filed ^{2/12/07}~~3/31/06~~ which have been considered by Examiner.

Foreign priority

Acknowledgment is made of applicants' claim for foreign priority based on a Japanese application: Japan 2002-255442 filed 8/30/2002. It is noted, however, that applicant has not filed the corresponding translation copy for said applications.

NOTE that the foreign priority filing date must antedate the reference and be perfected. The filing date of the priority document is not perfected unless applicant has filed a certified priority document in the application and an English language translation (if the document is not in English) (see 37 CFR 1.55(a)(3)). Perfecting a claim to priority under 35 U.S.C. 119(a)-(d) within the time period set in 37 CFR 1.55(a)(1) or filing a grantable petition under 37 CFR 1.55(c). See also MPEP § 201.13.

Applicant cannot rely upon the foreign priority papers to overcome the rejections under 35 USC 102 set forth below because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Objections to specification

(1) The instant application lacks continuing data at the first page of the specification.

(2) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code in page 6, line 15. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Applicants may remove "http://" so that the hyperlinker becomes inactive, i.e., the content preceded by Http:// can be and should be left behind; and thus, a browser will only interpret the rest of the URL as text.

(3) At page 7, lines 31-32, "antisense nucleotides" should be changed to "antisense nucleotide sequences" because "the polynucleotide" is composed of nucleotides.

(4) In the abstract, "LACS" should be spelled out in full.

Objections to claims

Claim 2, item c, lacks antecedent basis in the specification for the recitation "*a protein ... encoded by a polynucleotide that hybridizes ... with a polynucleotide comprising the nucleotide sequence of SEQ ID NO:2*" because said protein is encoded by antisense strand (i.e., the polynucleotide hybridizes (or complementary) to SEQ ID NO:2 that is the sense strand), and because the specification does not teach sets forth/teach that the antisense strand has ability of encoding a protein or a folded polypeptide (see also the discussion below with regard to written description).

Art Unit: 1656

Claims 6 and 7 are objected to because the “pharmaceutical” is a medicinal drug (molecule) molecule not a composition, and because the drug comprises the claimed polynucleotide only when they are linked together by a chemical bond. Applicants may want to use “formulation” (page 12, line 29) which is a composition to recite the pharmaceutical formulation comprising the polynucleotide thereof.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-3 and 6-7 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claim 2 and dependent claims thereto, as written, do not sufficiently distinguish over other polynucleotides or genes as they exist naturally because the claims do not particularly point out any differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. The claims should be amended to indicate the hand of the inventor, *e.g.*, by insertion of “isolated” as set forth in Example 1, page 16, line 29 of the specification. See MPEP 2105.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 2-3 and 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1656

Claim 1, step d, recites the term "homology". The specification does not define this term but rather refers it to Karlin et al. (*Proc. Natl. Acad. Sci.* (1993) 90, 5873-5877) (see page 6, line 12). This reference does not discuss or define nucleotide sequence "homology" but rather discusses statistic study of the combined scores of distinct sequence pairs; and thus, the specification fails to define the "homology" by the reference incorporated. Therefore, the metes and bounds of "homology" is unclear; does the "homology" refer to sequence identity or/and sequence similarity (to certain extent)?

Additionally, claim 1 does not make it clear whether or not the "a portion thereof" refers to the protein of item (a), or/and item (b), or/and item c, or/and item d thereof.

The dependent claims 3 and 6-7 are also rejected because these claims do not cure the defects of claim 1.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3 and 6-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed does not provide support for the invention as now claimed.

Art Unit: 1656

This is a **New Matter** rejection for the following reasons:

The claim 2 recitation “*having 60% homology to ...*” represents departure from the specification and the claims as originally filed. Although the specification (page 6, lines 5-6) sets forth that “homology of 50% or more” which includes 50% homology *per se*, but not necessarily encompasses 60% homology as the range “*or more*” may only cover 50% to 55%, for example. Thus, the “60% homology” has not been adequately described in the specification. The instant claims now recite limitation which was not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Written description

Claims 2-3 and 6-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP § 2163.

- Physical and/or chemical properties and partial structure:

In the instant case, the claims are drawn to a polynucleotide encoding L-NAME-related actin cytoskeletal protein (LACS), wherein "L-NAME" stands for "N^G-nitro-L-arginine methyl ester, hydrochloride", a widely used NO synthase inhibitor.

Claim 2, item d, sets forth a polynucleotide encoding a polypeptide having only 60% homology (not defined in the specification, see above) to amino acid sequence of SEQ ID NO:1 encoded by LACS polynucleotide of SEQ ID NO:2, wherein the "homology" encompasses peptide sequence similarity. Thus, "60% homology" reads on a large number of polynucleotide sequences. Further considering that "a portion" of said polypeptide which has 60% homology to SEQ ID NO:1, the claimed polynucleotide is drawn to a nucleotide sequence pool comprising enormous polynucleotides or oligonucleotides which structures are far diverse from instant SEQ ID NO:2 (LACS DNA) and even contain no structure of LACS DNA. The specification fails to describe these polynucleotides and oligonucleotides.

Claim 2, item c, sets forth a polynucleotide encoding a polypeptide which is encoded by a nucleotide sequence hybridizing under stringent condition with a polynucleotide comprising SEQ ID NO:2. Although, at page 6, lines 2-4, the specification describes the stringent condition at page 7, lines 15-19, the specification also sets forth that the polynucleotide comprising heterologous sequence (e.g., fusion protein and expression vector sequence) in addition that the polynucleotide comprise SEQ ID NO:2. Thus, the hybridization to said polynucleotide would result in heterologous nucleotide sequence(s) which structure is totally unrelated to instant SEQ ID NO:2.

Claim 2, item b, sets forth mutations such as deletion, insertion and substitution to the polypeptide or a *fragment* of the polypeptide encoded by the claimed polynucleotide or the a *subsequence* of the polynucleotide thereof. Such the mutated polynucleotide or oligonucleotide (resulted from said subsequence of the full-length SEQ ID NO:2) have not been adequately described by the instant disclosure.

- Functional characteristics:

The specification sets forth that the claimed nucleotide sequence can be *used* as probes or primers for detecting and amplifying DNAs and mRNAs encoding the corresponding proteins and also be *used* as antisense molecule for suppressing the expression of the protein encoded by LACS DNA of this invention (page 7, lines 27-33). The above-mentioned polynucleotides and oligonucleotides which are far diverse from LACS DNA of instant SEQ ID NO:2 may not have the uses discussed above because they are so structurally and functionally diverse from the full-length SEQ ID NO:2 that they even do not sequences necessary for said uses.

The specification sets forth that the “homology” (60% homology) is determined according to incorporated reference Karlin et al. According to Karlin et al. teachings, the instant “homology” is based on the score analysis wherein the scores are based on biochemical and physical properties of nucleotides/residues (right column, lines 6-7, page 5873), e.g., transmembrane scores (see Table 2, page 5875). Instant specification, however, fails to teach the biochemical and physical properties of disclosed polynucleotide on which the “homology” is based.

Claim 1, item (c), as written is directed to an antisense polynucleotide fragment partially complementary to the sense sequence of instant SEQ ID NO:2. This is because the “protein”

Art Unit: 1656

recited in item (c) is actually an antisense polypeptide encoded by a polynucleotide that hybridizes or complementary to the nucleotide sequence (sense strand) comprising SEQ ID NO:2. This would produce said antisense polynucleotide fragment. As discussed above, the hybridization to the polynucleotide comprising SEQ ID NO:2 will result in heterologous nucleotide sequence(s) totally unrelated to instant SEQ ID NO:2 which has no functional characteristics of the claimed polynucleotide. Therefore, applicants do not have possession of the polynucleotide recited in item c.

Claim 1, item b, as written is directed to enormous variants resulted from mutagenesis. The specification provide neither working example or teaching regarding the consensus sequence(s) nor functional domain(s) to which mutagenesis can be carried out without generating non-functional sequences.

- Level of skill and knowledge in the art:

The “homology” recited in claim 2 is in accordance with Karlin et al. reference (see above). This reference teaches that the paper describes the statistical distribution for the sum of the scores of multiple high scoring sequences (see abstract), and addresses that the greatest limitation on this statistics-analytic approach is the difficulty of deriving statistical distribution for tested sequences/segments (see left column, page 5873). Because of this difficulty, and because difficulty to predict properties and functions of LACA gene product from sequence alone (see instant specification, page 17, lines 10-12), the level of skill and knowledge is very high.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the

Art Unit: 1656

specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Scope enablement

Claims 2-3 and 6-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated polynucleotide comprising the full-length SEQ ID NO:2 which encodes LACS protein of SEQ ID NO:1, does not reasonably provide enablement for (i) the polynucleotide encoding "a portion" of SEQ ID NO:2, (ii) the polynucleotide encoding the polypeptide altered by mutagenesis: deletion, substitution, addition or/and insertion, and (iii) the polynucleotide encoding the polypeptide having 60% homology to SEQ ID NO:1 polypeptide, and (iv) any combination of (i), (ii) and (iii) thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte Forman*, 230 USPQ 546(BPAI 1986). They include the nature of the invention, the state of the art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

(1) The scope of the claims/(2) The nature of the invention:

The claims are broadly drawn to a large quantity of variant polynucleotides and/or oligonucleotides which are (i) the polynucleotide (fragment or subsequence) encoding “a portion” of SEQ ID NO:1 (claim 2, line 2), (ii) the polynucleotide encoding the polypeptide altered by mutagenesis: deletion, substitution, addition or/and insertion (claim 2, item b), and (iii) the polynucleotide encoding the polypeptide having 60% homology to SEQ ID NO:1 polypeptide (claim 2, item d), and (iv) any combination of (i), (ii) and (iii) thereof. The full-length polynucleotide of SEQ ID NO:2 is an actin cytoskeleton protein. Mutation (K610R substitution) to an actin cytoskeleton protein, yeast fimbrin, abolishes biological activity of fimbrin protein (see page 97, right column, Brower et al. (1995) *Genetics*, 140, 91-101). Screening for and characterization of the functional polynucleotides encoding biological functional protein required undue experimentation due to enormous amount of variants of the polynucleotides. In addition, since “60% homology” may refers to functional homology but not necessarily sequences identity (the instant “homology” relies upon the score analysis whereas the scores are based on biochemical and physical properties of nucleotides/residues (right column, lines 6-7, page 5873 of Karlin et al.), screening for and characterizing the polynucleotide having “60% homology” to the SEQ ID NO:2 require undue experimentation. Therefore, the scope of the claims is outside the bounds of the enablement.

(3) The unpredictability of the art:

The specification sets forth that level of expression of the LACS gene of SEG ID NO:2 is increased in response to the administration of NO inhibitor or hypertrophic agent; and LACS gene can be used to screen for compounds useful as pharmaceuticals for treating cardiovascular

Art Unit: 1656

disease (page 13, line 35 to page 16, line 2). Brower et al. teach that mutations of an actin cytoskeleton protein which is obtained by in vitro mutagenesis (page 98, right column, 2nd paragraph, line 4) show different levels of suppression, and some of them will abolish biological function of the encoded protein (see abstract and Tables 3-4, page 97). This suggests that the outcome of mutation such as substitution in the gene actin cytoskeleton protein thereof is unpredictable. Identifying the polynucleotide useful for screening for pharmaceuticals to treating disease state such as cardiovascular disease therefore requires undue level of experimentation.

(4) The state of the prior art:

The general knowledge in the art does not supplement the omitted teaching/description with regard to which subsequences or segments can be deleted and/or substituted (see the above discussion of the Brower et al. reference). Since it is difficult to predict the biochemical properties and functions of LASC encoded by the claimed LASC gene (page 17, lines 10-11, the specification), and since said properties and functions are required for administering gene therapy agents comprising the LACS gene (page 10, lines 25-27, the specification), the instant specification needs to provide the omitted teaching or description in this regard in order for enabling the claimed invention.

(5) The amount of direction/guidance:

The specification does provide neither guidance regarding how to use structurally unrelated nucleotide sequences as the pharmaceuticals (claims 6-7, and page 10, 4th paragraph), wherein the structurally unrelated (to the claims SEQ ID NO:2 polynucleotide) nucleotide sequence is resulted from (i) a portion of one or more nucleotides which have been modified by substitution, deletion, and/or addition/insertion; and (ii) a portion of polynucleotide hybridizing

Art Unit: 1656

to a polynucleotide that comprises heterologous sequence (encoding a fused polypeptide which is totally unrelated to instant SEQ ID NO:3 in nucleotide sequence) or vector sequence (see page 7, lines 15-19, the specification). Therefore, the amount of direction/guidance for enabling the claimed invention lacks. In the absence of the direction/guidance, one skilled in the art is unable to practice the claimed polynucleotide.

(6) The quantity of experimentation necessary:

As discussed above, the claimed polynucleotide encompasses enormous variants of polynucleotides or oligonucleotides: (i) the nucleotide fragment encoding “a portion” of SEQ ID NO:1, (ii) the mutated polynucleotide by mutagenesis: deletion, substitution, addition or/and insertion, and (iii) the polynucleotide having undefined sequence identity to instant SEQ ID NO:2 since the polynucleotide encoding the polypeptide having 60% homology to SEQ ID NO:1 have less than 60% sequence identity to SEQ ID NO:2 wherein “60% homology” (including *functional* homology *not* sequence identity, see the corresponding discussion above) reads on a large number of polynucleotide sequences. Sorting out and characterizing the functional polynucleotides thus requires undue experimentation.

(7) The relative skill of those in the art:

The level of skill in this art is high and requires at least a molecular biologist with several years of experience in mutagenesis, molecular biology as well as knowledge in pharmacology. Yet, even with a level of skill in the art as those mentioned in precedence, predictability of the results is still highly variable. An unduly level of skill is needed for the skilled artisan in order to screening for and characterizing the polynucleotides resulted from mutagenesis and/or 60%

Art Unit: 1656

homology based on statistical score-analysis (see above) which may produce the polynucleotide largely unrelated to the claimed SEQ ID NO:2 polynucleotide encoding LACS protein.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view of the quantity of experimentation necessary, the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention. Thus, the amount and level of experimentation needed is undue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- Claims 2 and 6-7 are rejected under 35 U.S.C. 102 (b) as being anticipated by Stanton et al. (WO 0174901 A2).

In the patent claim 1 (page 68, lines 7-10), Stanton et al. teach an isolated nucleic acid having clone Number "P00228_F03" encoding residues 121-239 of the polypeptide of SEQ ID NO:36 (see the sequence alignment shown by the attachment 2), wherein the peptide fragment of residues 121-239 is considered to be "a portion" of the polypeptide encoded by instant polynucleotide of SEQ ID NO:2, which anticipates instant claim 2.

Art Unit: 1656

At page 42, lines 30-35, Stanton et al. teach that the nucleic acid can be used as gene therapy agent, which anticipates instant claims 6-7. The reason for the rejection to claim 7 has discussed above.

- Claims 2 and 6-7 are rejected under 35 U.S.C. 102 (a) as being anticipated by Cros et al. (*J Cell. Biochem.* (2001) 83, 508-519).

Cros et al. teach a cDNA clone (Table I, page 511) which nucleotide sequence as 57.3% identity to instant SEQ ID NO:2 polynucleotide 9 (see the attachment 1), which anticipates claim 2.

Cros et al. teach the cDNA (novel gene) can be therapeutically useful for controlling muscle mass, i.e., used as a pharmaceutical, as applied to claim 6.

Claim 7 has the same structure or composition as the product of claim 6; the recitation “which is used to prevent, improve, or treat ...” is an intended use which has no patentable weight. Therefore, claim 7 is also rejected.

- Claim 2 is rejected under 35 U.S.C. 102 (b) as being anticipated by WO 2001/055326 A3 (this patent has no inventor name).

In the patent claim 1, WO 2001/055326 (326) disclose a nucleotide sequence of SEQ ID NO: 243 which nucleotides 2024-2547 are complementary to nucleotides 912-1435 of instant SEQ ID NO:2 polynucleotide (see the sequence alignment shown in the attachment 3). Since claim 1, item c, as written is directed to a polynucleotide segment hybridizing to (i.e., complementary to) a polynucleotide comprising instant SEQ ID NO:2, the patent 326 anticipates instant claim 2.

Art Unit: 1656

Conclusion

No claims are allowed.

Discussion of the art

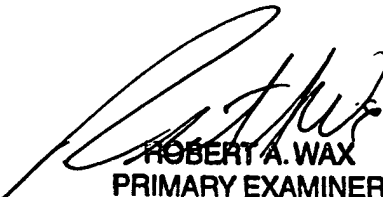
The prior art made of record and not currently relied upon in any rejections is considered pertinent to Applicants' disclosure:

- Karlin et al. (*Proc. Natl. Acad. Sci.* (1993) 90, 5873-5877) teach statistic study of the combined scores of distinct sequence pairs (protein or DNA).

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon, can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

swl
Samuel Wei Liu, Ph.D.
Art Unit 1656, Examiner
March 27, 2007


ROBERT A. WAX
PRIMARY EXAMINER